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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,348	02/14/2002	Jotham W. Coe	PC10030D	9919

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PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	PAPER NUMBER
1624	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/075,348	COE ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10,15-23 and 25-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,10,15-23 and 25-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6, 8, 10, 15-23 and 25-35 are pending in the application.

This action is in response to applicants' amendment filed November 7, 2006.

Response to Arguments

Applicants' arguments filed November 7, 2006 have been fully considered with the following effect:

1. The abandonment of copending Application No. 10/348,381 is sufficient to overcome the obviousness-type double patenting rejection of claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35, labeled paragraph 1) maintained in the last office action, which is hereby **withdrawn**.

2. With regards to the obviousness-type double patenting rejection of claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35, labeled paragraph 2) maintained in the last office action, the applicants' requested that this rejection be held in abeyance at this time.

Claims 1-6, 8, 10, 15-19, 22, 25-28 and 30-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/348,399, for reasons of record and stated above.

3. With regards to the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 3) maintained in the last office action, the applicants' amendments and remarks have been fully considered but they are not found persuasive. The applicants' stated that in view of the cited references, the individual of ordinary skill in the art would readily be

able to identify specific members of any of the aforementioned classes and formulate them with the active ingredient of the instant formula I using principles and procedures that are common knowledge in the art. However as stated in the office action dated May 19, 2005, the additional active ingredient within the terms a muscarinic agonist and an amyloid aggregation inhibitior is not defined in the specification. The terms are of indeterminate scope.

The nature of the instant invention, has claims which embrace substituted 10-aza-tricyclo[6.3.1.$0^{2,7}$]dodeca-2(7),3,5-triene compounds. The instant compounds of formula (I) wherein the additional active ingredients are not described in the disclosure in such a way the one of ordinary skill in the art would no how to prepare the various compounds suggested by claims 1-6, 8, 10 and 15-35. In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. The applicants' are not entitled to preempt the efforts of others. The test for determining compliance with 35 U.S.C. § 112 is whether the applicants have clearly defined "their" invention not what may be discovered by future research.

As stated in the MPEP, 2164.08 "[t]he Federal Circuit has repeatedly held that the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,

1561 27 USPQZd 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. In re Buchner, 929 F.2d 660, 661, 18 USPQZd 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a reasonable correlation to the scope of the claims. See, e.g., In re Fisher, 427 F.2d 833, 839,166 USPQ 18, 24 (CCPA 1970). As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQZd 1452, 1455 (Fed. Cir. 2003) (alleged pioneer status of invention irrelevant to enablement determination."

Claims 1-6, 8, 10, 15-23 and 25-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

4. With regards to the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 5a), b), c) and d) the applicant's amendments and remarks have been fully considered but they are not persuasive.

a) The applicants' stated that antecedent basis is found, for example, on page 1 of the specification, paragraph 2, lines 23-31. However, claim 25 is dependent upon claim 1 not the specification.

Claim 25 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

b) The applicants' stated that antecedent basis is found, for example, on page 1 of the specification, paragraph 2, lines 23-31. However, claim 26 is dependent upon claim 1 not the specification.

Claim 26 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

c and d) The applicants' stated that the declaration of Dane Liston, filed April 6, 2006, provides evidence that one skilled in the art would readily be able to identify specific members of any aforementioned narrow classes (i.e. muscarinic agonists and amyloid aggregation inhibitors) and thus one skilled in the art, having knowledge of the specific members of these narrow classes, would be reasonably apprised of the scope of the invention. However, claims 1-6, 8, 10, 15-23 and 25-35 generically claims the complex compositions where the additional active ingredient is a muscarinic agonist or an amyloid aggregation inhibitor. As stated in previous office actions the rejection of claims 1-6, 8, 10,

15-23 and 25-35 were on the grounds that it is indefinite, in that it is not known which diseases are capable of being responsive to the activity of muscarinic agonists or amyloid aggregation inhibitors. The claims are not directed to complex compositions where the additional active ingredient is not a narrow class but a class of compounds which possess muscarinic agonistic or amyloid aggregation inhibiting activity of which is not defined in the specification in such a way that one of ordinary skill in the art would be apprised of what compounds meet this criteria, thus the applicants have not set forth the metes and bounds of the claim.

Claim 1 and claims dependent thereon are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

Information Disclosure Statement

5. The information provided in the applicants remarks filed November 7, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Coleman

Brenda Coleman
Primary Examiner Art Unit 1624
January 10, 2007